4 April 2022
196-22

Call for submissions – Application A1244

Chymosin from GM *Trichoderma reesei* as a processing aid

FSANZ has assessed an Application made by Danisco New Zealand Ltd to amend the Australia New Zealand Food Standards Code to permit a new processing aid, chymosin, derived from a genetically modified strain of *Trichoderma reesei*, for use in the manufacture of certain dairy foods and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website via the link how to make a submission. You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 12 May 2022

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand

Food Standards Australia New Zealand

PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report

Executive summary

Danisco New Zealand Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to permit the use of chymosin (EC 3.4.23.4), sourced from a genetically modified (GM) strain of *Trichoderma reesei,* as a new processing aid for use in the manufacture of dairy foods. The enzyme is intended to be used in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products.

FSANZ has undertaken a risk and technical assessment. The technical assessment confirmed the use was appropriate and meet international purity specifications. Safety assessment including consideration of bioinformatics, toxicity and exposure assessment identified no public health and safety concerns.

After undertaking its risk and technical assessment, FSANZ concludes that there are no public health and safety concerns with the use of chymosin produced from a GM strain of *T. reesei,* expressing a chymosin gene from *Bos taurus* under the proposed use conditions.

As chymosin performs its technological function during food processing, not in the food for sale, FSANZ also concludes that if the draft variation is approved (i.e. if chymosin is listed in Schedule 18), chymosin would be a processing aid, as defined in the Code.

FSANZ has therefore prepared a draft variation to the Code, which if approved, would list the enzyme, chymosin sourced from *T. reesei* containing the chymosin gene from *Bos taurus*, in the table to subsection S18—9(3) of the Code as a permitted processing aid for use in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products. This permission would be subject to the condition that the amount of enzyme used must be consistent with GMP.

FSANZ seeks submissions on the draft variation.

1 Introduction

1.1 The Applicant

Danisco New Zealand Ltd is a subsidiary of International Flavors and Fragrances Inc (IFF) and is a manufacturer/marketer of specialty food ingredients, food additives and food processing aids based in New Zealand.

1.2 The Application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of chymosin (EC 3.4.23.4), sourced from a genetically modified (GM) strain of *Trichoderma reesei*, as a processing aid for use in the manufacture of dairy foods. This organism contains the chymosin gene from the domestic cow, *Bos taurus*. The enzyme is intended for use in the manufacture of cheese and cheese products and fermented and rennetted milk products. The applicant is requesting the approval of this chymosin, to perform the technological function of clotting milk by the highly specific cleavage of a single bond in the κ-chain of casein.

There is already an established history of use for chymosin in the manufacture of dairy foods (Garg and Johri 1995) and three other sources of chymosin are approved for use in the Code. Danisco has highlighted that approval would provide manufacturers with an additional choice of enzyme to facilitate the coagulation of casein, support effective production processes and reduce the use of raw materials.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Australia New Zealand Food Standards Code (the Code). The requirements relevant to this application are summarised below.

Permitted use

Enzymes used to process and manufacture food are considered processing aids. Although they may be present in the final food, they no longer provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a processing aid’ unless that substance’s use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance ‘used as a processing aid’ in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

Identity and purity requirements

Subsection 1.1.1—15(1)(b) of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019) and the United States Pharmacopeial Convention Food Chemicals Codex (12th edition, 2020).

Labelling requirements

Subsection 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Subsection 1.2.3—4(1) requires certain foods (foods listed in the table to section S9—3 or their derivatives e.g., cereals containing gluten, and sulphites added at a certain concentration level) to be declared when present in a food for sale. Paragraph 1.2.3—4(5)(c) states the food may be present as a substance used as a processing aid, or an ingredient or component of such a substance. Where the food to be declared is a substance used as a processing aid or an ingredient or component of such a substance, subsection 1.2.3—6(2) requires a declaration for the purposes of paragraph 1.2.1—8(1)(d) or subparagraph 1.2.4—5(6)(b)(i) to be made by (among other things) listing in the statement of ingredients of the food for sale the required name of the food to be declared and the words 'processing aid' in conjunction with that required name[1]. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7)).

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

Section 1.5.2—4 requires processing aids that are, or have as ingredients, foods produced using gene technology to be labelled 'genetically modified', where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a *genetically modified food*[2] (GM food). The requirements imposed by section 1.5.2—4 generally apply only to

[1] On 25 February 2021 the Code was amended to introduce new requirements for the labelling of allergens in food, including requirements for how to declare allergens when they are present in a food for sale. Suppliers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of the Code.

[2] Section 1.5.2—4(5) defines ***genetically modified food*** to mean a *food produced using gene technology that

foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15 respectively.

1.3.1 International standards

The Codex Alimentarius does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes established by JECFA and Food Chemicals Codex, as outlined above.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- it related to a matter that might be developed as a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure of the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

The purpose of the application is to amend Schedule 18 – Processing Aids of the Code to include chymosin (EC 3.4.23.4), sourced from a GM strain of *Trichoderma reesei.* This production organism contains the chymosin gene from the domestic cow, *Bos taurus*. Chymosin is proposed to be used as a processing aid in the manufacture of cheese and cheese products, and fermented and rennetted milk products. The enzyme preparation will be used according to Good Manufacturing Practice (GMP) conditions.

The evidence assessed provides adequate assurance that the enzyme, in the quantity and form (powder or liquid) proposed to be used, is technologically justified and achieves its stated purpose. The enzyme meets international purity specifications.

No public health and safety concerns were identified in the assessment of this chymosin sourced from a GM strain of *T. reesei* containing the chymosin gene from *Bos taurus* under the proposed use conditions. The host organism (*T. reesei)* is neither pathogenic nor toxigenic and has a long history of safe use in food. The gene donor organism (*Bos taurus)* has a history of safe use for food enzymes and raises no safety concerns. Analysis of the of the GM production strain (*T. reesei* t-AWL31) confirmed the presence and stability of the introduced DNA.

Chymosin produced by alternate GM hosts is already permitted in the Code. The results of bioinformatics searches showed no homology with known toxins or food allergens. The scientific literature includes cases of respiratory allergy to bovine rennet or chymosin, but no cases of allergic reactions in response to oral exposure. There is a substantial body of evidence that people can safely consume proteins to which they have a respiratory allergy.

(a) contains novel DNA or novel protein; or
(b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section" (*that being section 1.5.2—4*).

Wheat is used as a source of glucose for fermentation during production of the enzyme and will be labelled as required (see section 1.3 for more information).

No toxicology studies in animals have been conducted with this particular chymosin. Toxicity studies conducted on enzymes produced by related strains of *T. reeesei* include a number of studies in rodents, as well as genotoxicity assays. No adverse effects or evidence of pathogenicity were discovered in any of the rodent studies, and no evidence of mutagenicity or clastogenicity was discovered in any of the genotoxicity assays. The most closely related strain is one producing catalase, and for that enzyme, a no observed adverse effect level (NOAEL) of 700 mg total organic solids (TOS)/kg bw/day was identified in a 90-day oral toxicity study in rats. This value has been used for the calculation of a Margin of Exposure for chymosin, on the basis of Safe Strain Lineage. The theoretical maximum daily intake (TMDI) of this chymosin was calculated by FSANZ to be 0.125 mg TOS/kg bw. A comparison of the NOAEL and the TMDI results in a large Margin of Exposure (MOE) of approximately 5600.

Based on the reviewed data it is concluded that in the absence of any identifiable hazard an Acceptable Daily Intake (ADI) 'not specified' is appropriate. FSANZ concludes that there are no public health and safety concerns.

2.2 Risk management

The risk management options available to FSANZ after assessment, were to either:

- reject the application, or
- prepare a draft variation of the Code permitting chymosin (EC 3.4.23.4) sourced from a GM strain of *T. reesei* containing the chymosin gene from *Bos taurus*, to be used as a processing aid in cheese, cheese products, fermented milk products and rennetted milk products, subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

The Risk and Technical Assessment Report concluded that there are no safety concerns from using this enzyme for its stated purpose. In addition, the use of this enzyme, in the quantity and form (powder or liquid) proposed to be used, which must be consistent with GMP controls and processes, is technologically justified. Therefore, FSANZ has prepared a draft variation of the Code as outlined above (see Attachment A).

Other risk management considerations for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in Section 2.4.1.1 of this report take account of the safety of the enzyme.

2.2.1 Regulatory approval for enzymes

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme as a processing aid in cheese, cheese products, fermented milk products and rennetted milk products. The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)[3].

2.2.2 Enzyme nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB),

[3] Food produced using gene technology' is defined in subsection 1.1.2—2(3) as meaning 'a food which has been derived or developed from an organism which has been modified by gene technology'.

the internationally recognised authority for enzyme nomenclature, uses the ‘accepted’ name ‘chymosin’ for the enzyme with an EC number of EC 3.4.23.4 (IUBMB 1999). This is consistent with how chymosin is already permitted for use in the Code (using alternate gene hosts).

2.2.3 Labelling requirements

Subject to subsections 2.2.3.1 and 2.2.3.2 below, the generic exemption from listing processing aids in the statement of ingredients would apply to foods manufactured using this processing aid.

2.2.3.1 Labelling requirements for food produced using gene technology

Standard 1.5.2 in effect provides that a substance used as a processing aid that contains novel DNA or novel protein is a GM food. In contrast to the generic exemption for listing processing aids, subsection 1.5.2—4(2) states that the information relating to foods produced using gene technology must include the statement ‘genetically modified’ in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is used as a processing aid, the information may be included in the statement of ingredients.

The requirement for labelling as ‘genetically modified’ differs depending on whether the GM food is an ingredient of the food for sale or not. A food for retail sale or sold to a caterer that contains chymosin sourced from the GM *T. reesei* strain as an ingredient (e.g. the enzyme is used in the manufacture of cheese) would be required to be labelled ‘genetically modified’ in conjunction with the name of the enzyme.

FSANZ notes, however, that if the food made using the enzyme (e.g. cheese) is not a food for sale itself (e.g. an ingredient in a mixed food such as cheese powder on a biscuit), the enzyme would not be an ingredient in the food for sale. Therefore, the requirement for labelling as ‘genetically modified’ would not apply to chymosin in this case, because the labelling requirements only apply to food for sale that consists of, or has as an ingredient, a GM food (section 1.5.2—4(1)).

2.2.3.2 Declaration of certain substances

Glucose derived from wheat was used in the fermentation medium for the enzyme preparation, although the applicant states there is no allergenic risk associated with chymosin (Section 3.3.4 of SD1). If however wheat is present in the food for sale, it must be declared in accordance with requirements in Division 3 of Standard 1.2.3 (see Section 1.3 of this report).

2.2.4 Risk management conclusion

The risk management conclusion is to permit chymosin sourced from a GM strain of *T. reesei*, expressing a chymosin gene from *Bos taurus,* as a processing aid by amending the table to S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose would be for use in the manufacture of cheese, cheese products and fermented and rennetted milk products. The maximum permitted level would be an amount consistent with GMP. A mandatory declaration for wheat would apply if present in a food for sale to inform individuals that are allergic to wheat.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ’s standards development process. FSANZ developed

and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards (i.e. Codex Alimentarius Standards) and amending the Code to approve the enzyme as a processing aid is unlikely to have a significant effect on international trade.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considers permitting the use of chymosin sourced from GM *T. reesei* as a processing aid in manufacturing cheese, cheese products, fermented milk products and rennetted milk products.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme.

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at different conclusions.

Costs and benefits of permitting the use of enzyme chymosin (EC 3.4.23.4) sourced from a GM strain of T. reesei as a processing aid

Using the enzyme preparation from a GM strain of *T. reesei* may benefit industry by having additional choice of inputs to their manufacturing process especially if it proves cheaper, is more effective than what is presently available or results in additional competition among suppliers. Due to the voluntary nature of the permission, manufacturers would only use it where they believe a net benefit exists for them. Part of savings to the manufacturing industry may be passed on to consumers.

Permitting the enzyme to be used as a processing aid may result in a small cost to government in terms of adding this new substance to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme in question most likely outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand and there are no relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD1) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The labelling considerations for the enzyme processing aid are discussed in Section 2.2.3 of

this report.

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

- **the promotion of consistency between domestic and international food standards**

There are no Codex Alimentarius Standards for processing aids or enzymes. The enzyme processing aid meets international specifications for enzyme preparations, being the JECFA Combined Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report.

- **the desirability of an efficient and internationally competitive food industry**

The use of this enzyme is already permitted in the USA, Denmark, France and Mexico. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with the other countries where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the production microorganism or with using the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from this alternative enzyme for the various applications proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[4] includes specific order policy principles for substances added to achieve a solely

[4] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the ‘stated purpose’)
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of this enzyme is consistent with the specific order policy principles for ‘Technological Function’. All other requirements of the policy guidelines are similarly met.

3 Draft variation

The draft variation to the Code is at Attachment A and, if approved, is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1244 – Chymosin from GM *Trichoderma reesei* as a processing aid (enzyme)) Variation

---

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name and title of delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 2022. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1244 – Chymosin from GM* Trichoderma reesei *as a processing aid (enzyme)) Variation.*

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 18—Processing aids

[1] Subsection S18—9(3) (table)

Insert:

Chymosin (EC 3.4.23.4) sourced from *Trichoderma reesei* containing the chymosin gene from *Bos taurus*	For use in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products.	GMP

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1244 which sought permission to use chymosin (EC 3.4.23.4) from a genetically modified (GM) strain of *Trichoderma reesei* as a new processing aid for use in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme chymosin (EC 3.4.23.4) from a specific GM strain of *Trichoderma reesei* as a processing aid in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products. This permission would be subject to the condition that the amount of enzyme used must be consistent with

good manufacturing practice (GMP).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 23 (2019)) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1244 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Item [1] of the draft variation would insert a new entry into the table to subsection S18—9(3). The new entry would be inserted in alphabetical order and consist of the following enzyme:

- 'Chymosin (EC 3.4.23.4) sourced from *Trichoderma reesei* containing the chymosin gene from *Bos taurus*'

The permitted technological purpose for this enzyme would be use as a processing aid in the manufacture of cheese, cheese products, fermented milk products and rennetted milk products.

The permission would be subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

If approved, the draft variation would permit the proposed use of Chymosin (EC 3.4.23.4) sourced from *Trichoderma reesei* containing the chymosin gene from *Bos taurus* as a processing aid in accordance with the Code.